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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,841	08/11/2003	Peter C. Michels	20011/1474	4458

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/638,841

Applicant(s)

MICHELS ET AL.

Examiner

Celia Chang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 3-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This application is a continuation of SN 09/754,786. Claims 1-32 are pending.

Applicant's election without traverse of Group I, with *Stemphylium consortiale* as the elected species in the reply filed on Jan. 11, 2006 is acknowledged.

Based on the election, claims 2 and claims 1, 25-32 reading on claim 2 are prosecuted. Claims 3-24 are withdrawn from consideration per 37 CFR 1.142(b).

2. Claims 1-2, 25-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while provided description and being enabling for microorganism catalyzed oxidation employing the species of microorganism *Stemphylium consortiale*, does not reasonably provide description or enablement for all mutants or selectants of the microorganism embraced by the claims i.e. *Stemphylium* genera. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with these claims. Please note that it is unclear of what the scope of the claims are limited to. The genus as claimed encompassed any and all mutants or selectants (see p. 13, line 22) of the genus for which a bio-deposit has not been described or made. Applicants are urged to consult MPEP 2164.06 for enabling requirements of living microorganism.

Especially, in the instant operation, it is evidenced that even for microorganism readily available through public culture collection as stated on page 14, the operability of how the microbial culture was maintained would determine whether such "microbial source" is operable or not. Please note that for the same microbial species, dramatic variation of operability is observed when the biocatalyst is prepared from difference source. Therefore, no evidence in the record can support that the exemplification of one single *Stemphylium consortiale* can support any and all strand of *Stemphylium* especially on all possible mutants which have not been deposited per MPEP 2164.06.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azerad et al. WO 99/47693 in view of Humphrey et al. US 3,419,469, Herr et al. US 3,649,453, Charpentier et al. US 3,966,553, Goldberg et al. US 4,564,594, Page et al. US 5,032,513 or Witholt et al. US 5,135,859 further in view of Umezawa et al. CA 84:178218.

Determination of the scope and content of the prior art (MPEP §2141.01)

Azerad et al. '693 disclosed process of making the instant claimed compounds employing the instant claimed starting material by microorganism catalyzed oxidation/fermentation, and several species anticipating the generic claims were delineated supra (see section 3).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Azerad et al. '693 disclosed all the elements of the claims **except** variation of choices of microorganism was not expended. Humphrey et al. US 3,419,469 (col. 1, lines 47-50), Herr et al. US 3,649,453 (col. 1, line 18), Charpentier et al. US 3,966,553 (col. 1, line 46), Goldberg et al. US 4,564,594 (col. 2, lines 34-44), Page et al. US 5,032,513 (col. 9-10, examples 6-7) or Witholt et al. US 5,135,859 (col. 1, lines 53-col. 2 line 2) disclosed the claimed variety of microorganisms recognized in the art as choices in producing oxidative carboxylic acids from the precursor hydrocarbon starting material through fermentation processes. Umezawa et al. taught specifically, in microbial catalyzed oxidative processes, the *Stemphylium* genera and the *Streptomyces* genera of Azerad '693 would operate in analogous manner.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the available microorganism which are operable in fermentation oxidation processes to produce the carboxylic acid/ester of the corresponding hydrocarbon starting material. The choosing of the claimed particular genus of microorganism among the many conventional genus of microorganism known for such process is prima facie obvious in absence of unexpected results. The choice of *Stemphylium* i.e. the elected species has been particularly suggested, and the manipulation of parameters for optimization in production is an effect-oriented skill well within the skill of the chemical/fermentation artisan. Especially, the instant claims made no claim with respect to particularity of condition or parameter beyond the conventional standard operations in the field.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 1-2, 25-32 are rejected under 35 U.S.C. 101 because in so far as the elected invention being drawn to the species of *Stemphylium consortiale* is concerned, the claims are drawn to the same invention of issued claims 2, and 17-23 reading on 2 of US 6,613,907.

5. Claims 1-2, 25-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 17-32 of U.S. Patent No. 6,613,907. Although the conflicting claims are not identical, they are not patentably distinct from each other because were applicants' election intended to include the more limited scope of *Stemphylium consortiale* with operating temperature being 29°C, pH of 7 for a period of 168 hours, then the more limited scope is a prima facie limitation of the issued claims since such limitation is an effect oriented skill well within the skill of the chemical/fermentation artisan. Especially, the issued claims had no limitation with respect to particularity of condition or parameter beyond the conventional standard operations in the field.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Please note that the process of example 4 employing *Stemphylium consortiale* was described to be operated as the same condition as example 2 wherein the operating pH is 5. Therefore, were applicants' intention of election to include the particular limitation of operating

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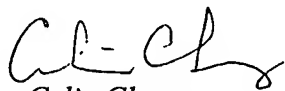
conditions, the elected pH 7 is new matter. A new matter rejection is hereby applicable to the claims were such election was to include the conditions as delineated on page 2 of the election response. Any amendment to the claims must not contain new matter.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Mar. 21, 2006


Celia Chang
Primary Examiner
Art Unit 1625